K100993

DEC 2 8 2010

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

A. SUBMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	4141 Mac Arthur Boulevard Newport Beach, CA 92660
Company Phone:	(949) 440-2683
Company FAX:	(949) 440-2787
Contact Person:	Kathleen Dragovich, (949) 399-1940
Date Summary Prepared:	December 20, 2010

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Inclusive® Titanium Abutments for- Astra OsseoSpeed™ Implants
21 CFR Reference:	872.3630
21 CFR Common Name:	Endosseous Dental Implant Abutment
Classification:	Class II
Panel:	Dental NHA

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:	Astra Tech AB OsseoSpeed™ Narrow, K081666 (10-07-08) Astra Tech Implant – Dental System, K990304 (07-15-99) Astra Tech Implant – Dental System, K931767 (02-08-94)

D. DEVICE DESCRIPTION

Inclusive® Titanium Abutments for- Astra OsseoSpeed™ Implants are endosseous implant abutments which are placed in to the dental implant to provide support for a prosthetic restoration. The subject abutments are indicated for cemented restorations. These abutments are made of titanium grade Ti-6Al-4V ELI (meets ASTM Standard F-136). The abutment is placed over the implant shoulder and is mounted into the implant with a screw. These abutments are compatible with the Astra OsseoSpeed™ Implants.

E. INDICATIONS FOR USE

The Inclusive® Titanium Abutments for Astra OsseoSpeed™ Implants are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Astra Tech OsseoSpeed™ 3.0, 3.5, 4.0, 4.5, 5.0 implants.

F. SUBSTANTIAL EQUIVALENCE

The Inclusive® Abutments for Astra OsseoSpeed™ Implants are substantially equivalent to the Atlantis™ Abutment for Astra Tech OsseoSpeed 3.0 Implant System, and the Astra Tech Implants Dental System Abutments. These abutments are substantially equivalent in intended use, indications for use, material, design and performance.

Element of Comparison	Prismatik's Inclusive® Abutments for Astra OsseoSpeed™ Implants	Astra Tech AB OsseoSpeed™ Narrow, K081666	Astra Tech Implant – Dental System, K990304
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	CP Titanium
Platform Diameters (mm)	3.0, 3.5, 4.0, 4.5, 5.0mm	3.0, 3.5, 4.0, 4.5, 5.0mm	3.0, 3.5, 4.0, 4.5, 5.0mm
Indications	The Inclusive® Titanium Abutments for Astra OsseoSpeed™ Implants are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Astra Tech OsseoSpeed™ 3.0, 3.5, 4.0, 4.5, 5.0 implants.	The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the maxillary lateral incisors and mandibular lateral and central incisors. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The device is compatible with the Astra Tech OsseoSpeed 3.0mm Implant	For use in selected fully edentulous and partially edentulous arches.
Design	Implant/Abutment assembly with abutment screw. Abutment connection to implant is an internal hexagon.	Implant/Abutment assembly with abutment screw. Abutment connection to implant is an internal hexagon.	Implant/Abutment assembly with abutment screw. Abutment connection to implant is an internal hexagon.
Performance	Fatigue testing conducted by Straumann® on stock Astra Tech TiDesign™ abutments and OsseoSpeed™ implants showed mean fatigue strength at 30° was around 110N and 125N for the 3.0 and 2.5mm implant diameters, respectively.	Fatigue testing conducted at Engineering Materials Laboratory on angled Inclusive® abutments and Astra Tech Osseospeed™ implants showed mean fatigue strength at 20° was 166.8N and 244.7N for the 3.0 and 3.5mm implant diameters, respectively. The higher fatigue strength results can be attributed to less angulation.	

G. PERFORMANCE DATA

Non-clinical test data was used to support the decision of safety and effectiveness. Clinical testing was not necessary. Non-clinical testing consisted of analysis of platforms to identify worst-case test samples and performance of fatigue testing of the worst-case samples in accordance with the FDA guidance Class II Special controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. The testing indicates that the device is safe and effective for its intended use and performs as well or better than the predicate device.

H. COMPARISON OF TECHNOLOGICAL DIFFERENCES

There are no known technological differences between the Inclusive® Titanium Abutments for- Astra OsseoSpeed™ Implants and those of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Kathleen Dragovich
Regulatory Affairs Specialist
Prismatik Dentalcraft, Incorporated
4141 Mac Arthur Boulevard
Newport Beach, California 92660

DEC 28 2010

Re: K100993
Trade/Device Name: Inclusive® Titanium Abutments for Astra OsseoSpeed™ Implants
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 20, 2010
Received: December 22, 2010

Dear Ms. Dragovich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

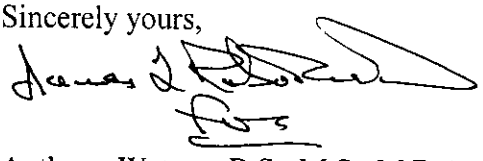
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PRISMATIK DENTALCRAFT, INC

Prismatik Dentalcraft, Inc.
4141 Mac Arthur Boulevard
Newport Beach, CA 92660

INDICATIONS FOR USE STATEMENT

DEC 2 8 2010

510(K) Number: K100993

Device Name: Inclusive® Titanium Abutments for Astra OsseoSpeed™ Implants

Indications for Use:

The Inclusive® Titanium Abutments for Astra OsseoSpeed™ Implants are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Astra Tech OsseoSpeed™ 3.0, 3.5, 4.0, 4.5, 5.0 implants.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

R Beth DDS for Dr Simon Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K100993